



Temporary supply shortage of Apidra® SoloSTAR® (insulin glulisine [rDNA origin] injection) pens in the United States

Dear Healthcare Professional,

We need to inform you of a temporary supply shortage of Apidra® SoloSTAR® pens in the United States, which may impact availability for your patients starting in late October 2011.

On July 11, 2011, a technical incident occurred at the Sanofi manufacturing site in Frankfurt, Germany. An in-depth investigation and additional controls were immediately carried out. This situation has caused temporary worldwide shortages. We have proactively notified the US Food and Drug Administration of the event in Frankfurt. In compliance with Good Manufacturing Practices, Sanofi is currently making every effort to resolve the issue. Following stringent quality tests, we expect to achieve normal supply levels by the first quarter of 2012.

Our investigation and controls have confirmed that Apidra® SoloSTAR® product currently on the market is not affected by the event. No other presentations of Apidra® and no other Sanofi insulin products, eg, Lantus® (insulin glargine [rDNA origin] injection), are affected.

While the shortage is in effect, one option that you might consider for patients using Apidra® SoloSTAR® pens is to switch them to Apidra® vials and syringes. In this case, there is no need for dose adjustment or changes in timing of injections. Please use your professional judgment on the need for patient training and guidance on syringe use to facilitate administration. Furthermore, self-monitoring of blood glucose (SMBG) is recommended.

Sanofi will provide support and education for patients and healthcare professionals to facilitate the appropriate handling of Apidra® vials and syringes during the temporary shortage situation. Support resources include:

- “How-to guide” to help patients learn appropriate handling of vials and syringes
- Video demonstrating use of vials and syringes
- Call center (**1-800-633-1610**) to provide guidance and support related to vial use
- Nurse support for patients who switch to Apidra® vials

Patient safety is the highest priority for Sanofi, and we are committed to providing high-quality insulins. We apologize for any inconvenience this shortage of Apidra® SoloSTAR® pens may cause. We are working diligently to minimize the impact of this situation on you and your patients, and we will provide relevant updates in a timely manner.

For further information, please do not hesitate to contact our call center at **1-800-633-1610**.

Best regards,

Robert Cuddihy, MD
Vice President Medical Head, US Medical Affairs